

REMARKS

The pending claims in this application are claims 6, 7, 9, 11-13, 16 and 28-31. The Office Action maintained the rejection of claims 6, 7, 9, 11, 12, 13, 16 and 28 under 35 USC 103(a) as being unpatentable over Lohray et al (WO 9741097). The Office Action has further maintained the objection to claims 29-31 as being dependent upon a rejected base claim.

The aim of the present invention is to provide a new composition with improved stability, particularly in solid dosage forms. It has been found that 5-[[4-[3-methyl-4-oxo-3,4-dihydro-2-quinazolinyl]methoxy]phenyl-methyl]thiadiazolidine-2,4-dione and its pharmaceutically acceptable salts may decompose in the presence of and in contact with water. Further, it has been observed that decomposing may occur in the presence of oxygen. The present invention is based on the surprising discovery of the fact that the stability of 5-[[4-[3-methyl-4-oxo-3,4-dihydro-2-quinazolinyl]methoxy]phenyl methyl]thiazolidine-2,4-dione, or its pharmaceutically acceptable salts, can be considerably improved in preparations containing of 5-[[4-[3-methyl-4-oxo-3,4-dihydro-2-quinazolinyl]methoxy]phenyl methyl] thiazolidine-2,4-dione or its pharmaceutically acceptable salts if the product is composed of excipients which have a low water content. Thus, to provide a stable composition the present invention discloses a composition wherein the carboxymethyl cellulose and corn starch are replaced by microcrystalline cellulose and the excipients used have low water content. The inventors of the present invention discovered that such formulation does not decompose in the presence of and in contact with water. Thereby an improved stability is achieved.

The Office Action appreciates that Lohray et al. does not teach the use of low water content. To remedy that acknowledged difference between the claimed invention and Lohray et al., the Office Action asserts that it would have been obvious to one of ordinary skill in the art to modify the composition in the Lohray et al. reference to employ any form of lactose because Lohray et al teach the composition comprising lactose in general. The Office Action further asserts that Lohray et al. utilize a cellulose derivative, carboxymethyl cellulose, which is has a viable utility as an excipient which is

closely related to microcrystalline cellulose and thus one of ordinary skill in the art would expect that compounds so closely related chemically would have the same or essentially the same properties.

Applicants' respectfully traverse this rejection and submit that the Office Action has failed to make a prima facie case of obviousness.

In determining whether a case of prima facie obviousness exists, it is necessary to ascertain whether the prior art teaching would appear to be sufficient to one of ordinary skill in the art to suggest making the substitution or modification to the cited art to arrived at the claimed invention. 35 U.S.C. § 103 (a) (1999); Graham v. John Deere Co., 383 U.S. 1, 14, 145 USPQ 459, 465 (1966). The mere possibility that the prior art could be modified is not a sufficient basis for a prima facie case of obviousness. See In re Brouwer, 77 F.3d 422, 425, 37 USPQ2d 1663, 1666 (Fed. Cir. 1996); In re Ochaiai, 71 F.3d 1565, 1570, 37 USPQ2d 1127, 1131 (Fed. Cir. 1995). The Office Action must explain why the prior art would have suggested to one of ordinary skill in the art the desirability of the modification. See In re Fritch, 972, F.2d 1260, 1266, 23 USPQ2d 1780, 1783-84 (Fed. Cir. 1992).

Furthermore, rejections based on §103(a) must rest on a factual basis with the facts being interpreted without hindsight reconstruction of the invention from the prior art. See In re Warner, 379 F.2d 1011, 1017, 154 USPQ 173, 177 (CCPA 19667) cert. denied, 389 U.S. 1057 (1968). The Federal Court has repeatedly cautioned against employing hindsight by using the inventor's disclosure as a blueprint to reconstruct the claimed invention from the isolated teaching of the prior art. See, e.g., Grain Processing Corp. v. American Maire-Products Co., 640 F.2d 902, 907, 5 USPQ2d 1788, 1792 (Fed. Cir. 1988).

In the present case, the Office Action has not established any convincing reason, suggestion or motivation for modifying Lohray et al. so as to arrive at the claimed subject matter.

The contention that it would have been obvious to one skilled in the art to modify a reference so as to arrive at the present invention is simply unsupported by the teachings of the prior art. See In re Kotzab, 217 F.3d 1365, 1371, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000). While it is true that the suggestion or motivation to modify a reference may

be implicit from the prior art as a whole rather than expressly stated, the Office Action must still provide reasons for finding a limitation to be taught or suggested in the references. Kotzab, 217 F.3d at 1370, 55 USPQ2d at 1316. In this regard, the Office Action has not established why one of ordinary skill in the art would choose to specifically replace the lactone and cellulose nor has the Office Action established why a person of ordinary skill in the art would view Lohray et al. as requiring any correction or modification.

Lohray et al. do not teach, disclose or suggest the desirability for making the tablet more stable by using anhydrous lactose and microcrystalline cellulose as taught in the present invention. Hence, the Office Action has not established the requisite motivation for one of ordinary skill in the art to modify Lohray et al.

In sum, modifying Lohray et al. can only be based upon improper hindsight reasoning. See, W. L. Gore & Associates v. Garlock, Inc., 721 F.2d 1540, 1553, 220 USPQ 303, 312-13 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984) (“To imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher.”) In addition, when it is necessary to selectively modify the prior-art reference in order to render obvious a subsequent invention, there must be some reason for the modification other than the hindsight gleaned from the invention itself. There must be some teaching in the prior art as a whole to suggest the desirability, and thus the obviousness of modifying the referenced art. Uniroyal Inc. v. Rudkin-Wiley Corp., 3 USOQ2d 1434 (Fed. Cir. 1988)

Applicants submit that the Lohray reference is at most an invitation to experiment. Even if it were "obvious to try" to construct Applicants' claimed invention, which Applicants emphatically do not concede, such an "obvious to try" standard has been repeatedly rejected as an improper basis for a rejection under 35 U.S.C. 103. E.g., In re O'Farrell, 7 USPQ2d 1673, 1681 (Fed.Cir. 1988); In re Fine, 5 USPQ2d 1596, 1599 (Fed. Cir. 1987). However, as was stated in In re Dow Chemical, 5 USPQ2d 1529, 1532 (Fed.Cir. 1988), this is not an appropriate test of obviousness:

"The PTO presents, in essence, an 'obvious to experiment' standard for obviousness. However, selective hindsight is no more applicable to the design of experiments than it is to the combination of prior art teachings. There must be a teaching or suggestion in the art for selecting the procedure used, other than the knowledge learned from the applicant's disclosure."

The Office Action reliance on Lohray et al. fails to meet the test set forth in Dow.

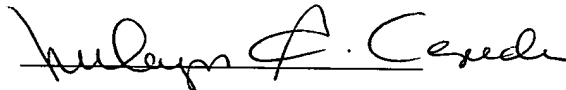
Claims 7, 9, 11, 12, 13, 16, 28 and 29-31 depend from claim 6 and define additional limitations to the material. Further, since these claims depend from claim 6 it is believed to that these claim are allowable at least for the same reasons that claim 6 allowable. Applicants therefore requests withdrawal of the rejection of claims 6, 7, 9, 11, 12, 13, 16, and 28-31.

In view of the foregoing remarks, Applicants submits that the pending claims particularly define and patentably distinguish the invention over the art of record, and request that the Rejection be withdrawn and that this case is passed to issuance. Should the Office believe that further issues remain to be resolved it is requested that she telephone the undersigned in order to provide the Applicants with an opportunity to resolve such issues.

Respectfully submitted,

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Date



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